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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,987	10/31/2006	James Carlyon	1502-84PCTUSCIP	8863

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EXAMINER	
PRICE, NATHAN R	

ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
12/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,987	CARLYON ET AL.	
	Examiner	Art Unit	
	NATHAN R. PRICE	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/18/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-22 and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 7226434. Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations of claims 1-22 and 25 of the current application are included in claims 1-24 of the patent. Furthermore, claim 11, which depends on claim 9 and claim 1 in the current application, was indicated allowable in previous patent 7226434, and allowed as claim 24. Therefore, claims 1, 9, and 11, if incorporated together in the same way as in the previous patent to form an allowable claim, would result in a statutory double patenting rejection.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-10, 12-22, 25-29, 31, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Woehr et al. (US 6287278).

3. Regarding claims 1-5, Woehr et al. discloses a safety shield comprising: a piercing member 16 (fig. 1a) having a distal end and defining a longitudinal axis;

and a clip (shown in fig. 1a and 1b) defining a first cavity 58 (fig. 1a) dimensioned for movement of the piercing member therethrough and being oriented in an axis transverse to the longitudinal axis of the piercing member, the first cavity being movable between a movable orientation (fig. 1a) and a binding orientation (fig. 1b); the clip including a first leg (extending between points 50 and 52, fig. 1a) that defines a second cavity 56 (fig. 1a) dimensioned for movement of the piercing member therethrough and a distal part 46 (fig. 1a) being configured to engage a medical device 30 (fig. 1a), the clip further including a second leg 42 (fig. 1a) having a bearing surface 44 (fig. 1a) that engages the piercing member; wherein the first leg and the second leg are biased for convergent movement (such movement seen by comparing fig. 1a to fig. 1b) such that the first cavity is disposed in the binding orientation and the distal part of the first leg disengages the medical device (as shown in fig. 1b); the first cavity is rotatable relative to the longitudinal axis (see fig. 1a and 1b) and defines a binding surface that engages the piercing member in a binding orientation (binding surface being the inner surface of cavity 58, shown in binding orientation in fig. 1a); the clip includes a plate 40 (fig. 1a) that defines the first cavity and is oriented substantially perpendicular to the legs; and the first leg has a proximal part that is oriented substantially perpendicular to the transverse axis of the first cavity in the moveable orientation (it is considered that the proximal part of first leg 40 is substantially perpendicular to the transverse axis of the first cavity 58, fig. 1a and 1b). See also col. 4, ln. 56 through col. 5, ln. 63.

4. Regarding claims 6-10 and 12-14, Woehr et al. discloses the second leg has a proximal part that is oriented substantially perpendicular to the transverse axis of the first cavity in the moveable orientation (second leg 44 has a proximal part that is perpendicular to the transverse axis of the first cavity); the distal part of the first leg includes a transverse portion that defines the second cavity (the first leg has a transverse portion that defines second cavity 56); the distal part of the first leg includes an arm configured to releasably retain the medical device (distal part 46 of first leg is an arm); the housing includes a flash chamber 22 (fig. 1a); and the medical device includes a catheter 24 (fig. 1a). See also col. 4, ln. 56 through col. 5, ln. 63.

5. Regarding claims 15-22 and 25, Woehr et al. discloses the elements as noted above as well as a housing (located at proximal end of piercing element 16, and comprising elements 12 and flash chamber 22, as shown in fig. 1b) having an outer surface; the piercing member is disposed within the cavity of the first leg (see fig. 1a) to prevent convergent movement of the legs; the distal part 46 of the first leg is an arm configured to releasably retain the medical device 30 with the outer surface of the housing (see fig. 1a and 1b; in fig. 1b, the housing is shown connected to piercing element 16, and in fig. 1a, the arm retains the medical device 30 in contact with the outer surface of the housing via interaction with piercing element 16). See also col. 4, ln. 56 through col. 5, ln. 63.

6. Regarding claim 26-29, 31, and 33, Woehr et al. discloses the elements as noted above as well as a cavity defined by the second leg (area between second leg 42 and piercing member 16 shown in fig. 1A and 1B) that is rotatable

between a moveable (fig. 1A) and a binding (fig. 1B) orientation, defining a binding surface that engages the piercing member in the binding orientation (shown in fig. 1B, where inner surface of cavity defined by second leg engages needle tip 18 if needle movement is attempted).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woehr et al. in view of Ferguson (US 20020193745).

9. Regarding claims 23 and 24, Woehr et al. discloses the apparatus as claimed except for the first cavity includes a slot, and the cavity of the plate includes a slot configuration. However, Ferguson teaches a safety shield cavity in the form of a slot (fig. 8). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Woehr et al. apparatus such that the first cavity includes a slot, and the cavity of the plate includes a slot configuration, as taught by Ferguson, for the purpose of permitting a guidewire or stylet to pass through the bore (par. 0058).

10. Claims 30, 34-36, and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woehr et al.

11. Regarding claims 30 and 34, Woehr et al., in fig. 1A and 1B, discloses the apparatus as claimed except for the flared orientation of the binding surfaces. However, Woehr et al. teaches a flared orientation used in the second cavity in an alternate embodiment (fig. 7A-9; flare 118 visible in fig. 9 and shown in engagement in fig. 7C). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Woehr et al. apparatus such that the first cavity's binding surface has a flared orientation, as taught by Woehr et al.'s fig. 7A-9, for the purpose of improving the retention characteristics of the binding surface.

12. Regarding claims 35, Woehr et al., in fig. 1A and 1B, discloses the apparatus as claimed except for a distal portion of the second leg releasably engages a catch of the first leg to facilitate movement of the piercing member in the moveable orientation. However, Woehr et al. teaches a second leg distal portion 67 (fig. 4A-B) engaging a catch (opening 80, fig. 4A-B) in order to facilitate movement in the moveable orientation (which is shown in fig. 4A). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Woehr et al. apparatus of fig. 1A and 1B such that a distal portion of the second leg releasably engages a catch of the first leg to facilitate movement of the piercing member in the moveable orientation, as taught by fig. 4A and 4B, for the purpose of improving the retention characteristics of the binding surface.

13. Regarding claim 36, Woehr et al., in fig. 1A and 1B, discloses the apparatus as claimed except for a distal portion of the second leg has a catch

that releasably engages and is disposed within a channel defined within the first leg, in the moveable orientation. However, Woehr et al. teaches a catch (curved area 67, fig. 4A-B) releasably engaging and disposed within a channel 80 (fig. 4A-B) in the first leg in a moveable orientation (shown in fig. 4A). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Woehr et al. apparatus of fig. 1A and 1B such that a distal portion of the second leg has a catch that releasably engages and is disposed within a channel defined within the first leg, in the moveable orientation, as taught by fig. 4A and 4B, for the purpose of improving the retention characteristics of the binding surface.

14. Regarding claims 38-40, Woehr et al. discloses, in fig. 1a-1b, the apparatus as claimed except for a network of biasing elements configured to bias the clip defining channels therebetween and connected to form a continuous spring. However, in fig. 12, Woehr et al. teaches a clip comprising a network of biasing elements 160 and 162 defining channels therebetween and continuously formed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Woehr et al. apparatus of fig. 1a and 1b such that a network of biasing elements is configured to bias the clip defining channels therebetween and connected to form a continuous spring, as taught by fig. 12, for the purpose of providing sufficient biasing force to increase the security of the piercing element within the safety shield.

15. Claims 32 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woehr et al. in view of Ferguson et al. (US 20020151850).

16. Regarding claim 32 and 37, Woehr et al. discloses the apparatus as claimed except for a second transverse portion with an aperture aligned with that of the first transverse portion. However, Ferguson et al. teaches a distal part a second transverse portion 38 with an aperture aligned with aperture 22 in the adjacent transverse portion (fig. 3A). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Woehr et al. apparatus such that it comprises a second transverse portion with an aperture aligned with that of the first transverse portion, as taught by Ferguson et al., for the purpose of reinforcing the engagement between the shield and piercing member.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN R. PRICE whose telephone number is (571)270-5421. The examiner can normally be reached on Monday-Thursday, 7:00 a.m. - 4:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. P./
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763